

data and records including, but not limited to, the following:

- (1) Participant health outcomes data.
- (2) Financial books and records.
- (3) Medical records.
- (4) Personnel records.

(c) *Reporting.* A PACE organization must submit to CMS and the State administering agency all reports that CMS and the State administering agency require to monitor the operation, cost, quality, and effectiveness of the program and establish payment rates.

(d) *Safeguarding data and records.* A PACE organization must establish written policies and implement procedures to safeguard all data, books, and records against loss, destruction, unauthorized use, or inappropriate alteration.

(e) *Confidentiality of health information.* A PACE organization must establish written policies and implement procedures to do the following:

(1) Safeguard the privacy of any information that identifies a particular participant. Information from, or copies of, records may be released only to authorized individuals. Original medical records are released only in accordance with Federal or State laws, court orders, or subpoenas.

(2) Maintain complete records and relevant information in an accurate and timely manner.

(3) Grant each participant timely access, upon request, to review and copy his or her own medical records and to request amendments to those records.

(4) Abide by all Federal and State laws regarding confidentiality and disclosure for mental health records, medical records, and other participant health information.

(f) *Retention of records.* (1) A PACE organization must retain records for the longest of the following periods:

- (i) The period of time specified in State law.
- (ii) Six years from the last entry date.
- (iii) For medical records of disenrolled participants, 6 years after the date of disenrollment.

(2) If litigation, a claim, a financial management review, or an audit arising from the operation of the PACE program is started before the expiration of the retention period, specified

in paragraph (f)(1) of this section, the PACE organization must retain the records until the completion of the litigation, or resolution of the claims or audit findings.

#### **§ 460.202 Participant health outcomes data.**

(a) A PACE organization must establish and maintain a health information system that collects, analyzes, integrates, and reports data necessary to measure the organization's performance, including outcomes of care furnished to participants.

(b) A PACE organization must furnish data and information pertaining to its provision of participant care in the manner, and at the time intervals, specified by CMS and the State administering agency. The items collected are specified in the PACE program agreement.

#### **§ 460.204 Financial recordkeeping and reporting requirements.**

(a) *Accurate reports.* A PACE organization must provide CMS and the State administering agency with accurate financial reports that are—

(1) Prepared using an accrual basis of accounting; and

(2) Verifiable by qualified auditors.

(b) *Accrual accounting.* A PACE organization must maintain an accrual accounting recordkeeping system that does the following:

(1) Accurately documents all financial transactions.

(2) Provides an audit trail to source documents.

(3) Generates financial statements.

(c) *Accepted reporting practices.* Except as specified under Medicare principles of reimbursement, as defined in part 413 of this chapter, a PACE organization must follow standardized definitions, accounting, statistical, and reporting practices that are widely accepted in the health care industry.

(d) *Audit or inspection.* A PACE organization must permit CMS and the State administering agency to audit or inspect any books and records of original entry that pertain to the following:

(1) Any aspect of services furnished.

(2) Reconciliation of participants' benefit liabilities.